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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,497	05/01/2001	Amina Odidi	9577-25 LAB	2340

7590 12/30/2005
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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,497

Applicant(s)

ODIDI ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11,15-17 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,6-9,11,15,16,22,24-29,31,32 and 34 is/are allowed.
- 6) ☒ Claim(s) 17,21,23,30 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

I. Objection to specification regarding "microcrystalline cellulose as an extrusion aid" being new matter is withdrawn in light of amendment filed 9/26/05. Applicant has removed reference to "microcrystalline cellulose" as being an extrusion aid.

II. Rejection of claims 1,6-9,11,15-17,21-34 under 35 USC 112, 1st paragraph will not be maintained in light of amendment filed 9/26/05. Applicant has removed reference to "microcrystalline cellulose" as being an extrusion aid.

III. Declaration dated 11/17/04 attest to cellulose acetate as encasement coating being insoluble at pH above 5.0, whereas, methacrylic/methacrylate polymers being soluble at pH above 5.0. Examiner argues that claims are not limited to cellulose acetate as the encasement coat. In addition, the rejection in section IV uses ethyl cellulose as encasement coat.

IV. New Ground of Rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17,21,23,30,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirashima et al (JP 03197421; 8/28/91). Hirashima teaches a controlled release tablet coated with 12 g ethyl cellulose and 8 g PEG (40 %). Hirashima teaches that the tablet comprises 250 mg ascorbic acid and 281.23 mg

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sodium ascorbate (total active = 531.23 mg). The total active falls within the 5-95% active required for the tablet of instant claims. The coat comprising 12 g ethyl cellulose falls within the range of about 5 to less than 50% by weight of polymer in the coat. Hirashima does not teach that the coating is non-permeable and soluble in a pH of above about 5. However, in the absence of unexpected results, one having ordinary skill in the art would have expected for the prior art coat to be non-permeable and soluble in a pH of above about 5. One would have expected this since the prior art coat comprises % PEG and % polymer (ethyl cellulose) that fall within the ranges of those ingredients required by the instant claims.

Allowable Subject Matter

Claims 1,6-9,11,15,16,22,24-29,31,32,34 are allowable. The prior art does not teach or suggest the instantly coated tablets comprising both instant extrusion as well as compression aids.

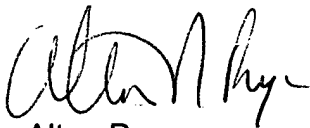
Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is positioned above the printed name.

Alton Pryor
Primary Examiner
AU 1616